

116TH CONGRESS
1ST SESSION

H. R. 321

To amend the Public Health Service Act to create a National Neuromyelitis Optica Consortium to provide grants and coordinate research with respect to the causes of, and risk factors associated with, neuromyelitis optica, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

JANUARY 8, 2019

Ms. LEE of California introduced the following bill; which was referred to the Committee on Energy and Commerce

A BILL

To amend the Public Health Service Act to create a National Neuromyelitis Optica Consortium to provide grants and coordinate research with respect to the causes of, and risk factors associated with, neuromyelitis optica, and for other purposes.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Neuromyelitis Optica
5 Consortium Act”.

6 **SEC. 2. FINDINGS.**

7 Congress finds the following:

1 (1) Neuromyelitis optica (NMO) is a dev-
2 astating neurologic disease leading to blindness and
3 paralysis.

4 (2) There are an estimated 16,000 to 17,000
5 people with NMO in the United States and a quar-
6 ter-million worldwide.

7 (3) Women are affected 4 to 5 times more than
8 men, and Afro-Caribbeans are about 2.5 times more
9 predisposed to NMO than Caucasians. The reasons
10 why Blacks are disproportionately affected cannot be
11 fully understood without further studies.

12 (4) The average age at diagnosis is between 40
13 and 50 years, but the range is broad and includes
14 children as young as 3 years of age and adults as
15 old as 90 years of age.

16 (5) NMO incurs substantial costs for affected
17 patients and their families.

18 (6) The cause of NMO is unknown, but it is hy-
19 pothesized to be autoimmune in nature.

20 (7) More than 90 percent of NMO patients will
21 suffer recurrent disease and accumulate neurologic
22 disability.

23 (8) Because of their relatively low overall inci-
24 dence, orphan diseases like NMO frequently do not
25 receive sufficient attention and research funding.

1 (9) No single institution has a sufficient num-
2 ber of patients to independently conduct research
3 that will adequately address the cause of NMO.

4 (10) There has been no comprehensive study
5 analyzing all relevant clinical, biological, and epide-
6 miological aspects of NMO to identify potential risk
7 factors and biomarkers for NMO.

8 (11) We can apply our understanding of NMO
9 to the study of other autoimmune diseases, including
10 multiple sclerosis and systemic lupus erythematosus.

11 **SEC. 3. SENSE OF CONGRESS.**

12 It is the sense of Congress that there is a need—

13 (1) to establish and coordinate a multicenter re-
14 search effort based on collaboration between regional
15 consortia and governmental and nongovernmental
16 entities in order to—

17 (A) comprehensively study the causes of
18 NMO; and

19 (B) identify potential biomarkers of disease
20 activity; and

21 (2) to encourage a collaborative effort among
22 academic medical centers with epidemiological study
23 groups to gather comprehensive and detailed infor-
24 mation for each patient enrolled in those groups, in
25 order to investigate environmental, nutritional, and

1 genetic factors with respect to, and the pathological
 2 and epidemiological characteristics of, NMO.

3 **SEC. 4. ESTABLISHMENT OF THE NATIONAL NEUROMYELI-**
 4 **TIS OPTICA CONSORTIUM.**

5 Part B of title IV of the Public Health Service Act
 6 (42 U.S.C. 284 et seq.) is amended by adding after section
 7 409J the following new section:

8 **“SEC. 409K. NATIONAL NEUROMYELITIS OPTICA CONSOR-**
 9 **TIUM.**

10 “(a) ESTABLISHMENT OF THE NATIONAL
 11 NEUROMYELITIS OPTICA CONSORTIUM.—

12 “(1) IN GENERAL.—Not later than 1 year after
 13 the date of the enactment of this section, the Sec-
 14 retary, acting through the Director of NIH, and in
 15 coordination with the Director of the National Insti-
 16 tute on Minority Health and Health Disparities,
 17 shall establish, administer, and coordinate a Na-
 18 tional Neuromyelitis Optica Consortium (in this sec-
 19 tion referred to as the ‘NNO Consortium’) for the
 20 purposes described in paragraph (2).

21 “(2) PURPOSES.—The purposes of the NNO
 22 Consortium shall be the following:

23 “(A) Providing grants of not fewer than 5-
 24 years’ duration to eligible consortia for the pur-
 25 pose of conducting research with respect to the

1 causes of, and the risk factors and biomarkers
2 associated with, NMO.

3 “(B) Assembling a panel of experts to pro-
4 vide, with respect to research funded by the
5 NNO Consortium, ongoing guidance and rec-
6 ommendations for the development of the fol-
7 lowing:

8 “(i) A common study design.

9 “(ii) Standard protocols, methods,
10 procedures, and assays for collecting from
11 individuals enrolled as study participants a
12 minimum dataset that includes the fol-
13 lowing:

14 “(I) Complete medical history.

15 “(II) Neurologic examination.

16 “(III) Biospecimens, including
17 blood, spinal fluid, DNA, and RNA.

18 “(IV) Radiological data, includ-
19 ing magnetic resonance imaging
20 (MRI).

21 “(iii) Specific analytical methods for
22 examining data.

23 “(iv) Provisions for consensus review
24 of enrolled cases.

1 “(v) An integrated data collection net-
2 work.

3 “(C) Designating a central laboratory to
4 collect, analyze, and aggregate data with re-
5 spect to research funded by the NNO Consor-
6 tium and to make such data and analysis avail-
7 able to researchers.

8 “(3) ELIGIBLE CONSORTIA.—To be eligible for
9 a grant under this section, a consortium shall dem-
10 onstrate the following:

11 “(A) The consortium has the capability to
12 enroll as research participants a minimum of 25
13 individuals with a diagnosis of NMO from the
14 consortium’s designated catchment area.

15 “(B) The designated catchment area of the
16 consortium does not overlap with the designated
17 catchment area of another consortium already
18 receiving a grant under this section.

19 “(4) REPORT.—Not later than 1 year after the
20 date of the enactment of this section, and annually
21 thereafter, the Secretary, acting through the Direc-
22 tor of NIH, shall submit to Congress a report with
23 respect to the NNO Consortium, to be made publicly
24 available, including a summary of research funded
25 by the NNO Consortium and a list of consortia re-

ceiving grants through the NNO Consortium. At the discretion of the Secretary, such report may be combined with other similar or existing reports.

“(5) AUTHORIZATION OF APPROPRIATIONS.—

“(A) IN GENERAL.—There is authorized to be appropriated \$25,000,000 for each of fiscal years 2019 through 2022, to remain available until expended, to carry out this section.

“(B) SENSE OF CONGRESS.—It is the sense of Congress that funds appropriated to carry out this section should be in addition to funds otherwise available or appropriated to carry out the activities described in this section.

“(b) DEFINITIONS.—For purposes of this section:

“(1) CATCHMENT AREA.—The term ‘catchment area’ means a defined area for which population data are available.

“(2) CONSORTIUM.—The term ‘consortium’ means a partnership of two or more universities, health care organizations, or government agencies, or any combination of such entities, serving a designated catchment area.”.

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